

EXHIBIT H

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1 UNITED STATES DISTRICT COURT
2 DISTRICT OF MASSACHUSETTS
3 No. 05-cr-10088-EFH-1

4
5 UNITED STATES OF AMERICA
6
7 vs.
8 RUDOLPH J. LIEDTKE and RJL SCIENCES, INC.
9

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11 *****
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13 For Plea Hearing Before:
14 Honorable Edward F. Harrington

15 United States District Court
16 District of Massachusetts (Boston.)
17 One Courthouse Way
18 Boston, Massachusetts 02210
Tuesday, April 19, 2005

19 *****
20

21 REPORTER: RICHARD H. ROMANOW, RPR
22 Official Court Reporter
United States District Court
23 One Courthouse Way, Room 3507, Boston, MA 02210
(617) 737-0370
24

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1 A P P E A R A N C E S
2

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1 P R O C E E D I N G S

2 (Begins 2:00 p.m.)

3 THE CLERK: Criminal Action 05-10088, United States
4 versus R. J. Liedtke, et al.

5 THE COURT: I'm sorry to be late. I had a
6 meeting. But I'll hear from the Government.

7 MS. CARMODY: Good afternoon, your Honor. My name
8 is Mary Elizabeth Carmody, Assistant United States Attorney.
9 And with me today is Sondra Mills, a trial attorney from the

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10 Department of Justice. We're here today for an arraignment and
11 an entry of a plea of guilty by the defendant, both the
12 corporation and the individual, to the information. The
13 defendant has agreed to waive indictment, your Honor. I have
14 simply forgotten to bring the form with us. So that Counsel
15 has agreed that we will sign it and file it as soon the hearing
16 is concluded. Other than that, your Honor, we're ready to go
17 forward on a Rule 11 hearing as well as an agreement.

18 THE COURT: My understanding is that a Crawford
19 defendant is involved?

20 MS. CARMODY: Yes, your Honor.

21 THE COURT: And who is going to plea on behalf of
22 the Crawford defendant?

23 MR. LOPEZ: Your Honor, good afternoon. Scott
24 Lopez on behalf of Rudolph Liedtke, RJL Sciences, Inc. I've
25 filed a notice of appearance in this matter and I've also filed

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1 a motion to admit Attorney Robert Kalec pro hac vice. At this
2 time I would move to -- I would move this court to allow him to
3 appear pro hac vice.

4 THE COURT: Okay.

5 MR. LOPEZ: And with that I'll turn the microphone
6 over to Mr. Kalec, so to speak.

7 MR. KALEC: Good afternoon, your Honor.

8 Mr. Liedtke appears today on his personal behalf and also as
9 President and principal owner of RJL Sciences and he will
10 represent the corporation, in its corporate capacity, today for
11 the plea.

12 THE COURT: And how big a corporation is it?

13 MR. KALEC: Including himself, it has six
14 employees, your Honor.

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15 THE COURT: And does anyone else own the
16 corporation?

17 MR. KALEC: There are four other minority owners,
18 your Honor.

19 THE COURT: And has the -- does it have a board of
20 directors?

21 MR. KALEC: It does, your Honor. And we had
22 submitted to the prosecution a corporate resolution authorizing
23 Mr. Liedtke to appear on behalf of the corporation and to enter
24 into the Rule 11 agreement.

25 MS. CARMODY: And we filed a corporate resolution

1 today, your Honor.

2 THE COURT: All right. Prior to accepting any plea

3 of an individual nature or on behalf of the corporation, I wish

4 to ask the individual defendant certain questions. You are

5 going to answer these questions both on your own behalf and on

6 behalf of the corporation.

7 THE DEFENDANT: Yes, your Honor.

8 THE COURT: I want to advise you as to certain
9 constitutional rights. You have a constitutional right to a
10 speedy, public trial by jury. Do you understand that?

11 THE DEFENDANT: Yes.

12 THE COURT: You have a constitutional right to see
13 and hear the evidence against you and to cross-examine
14 witnesses against you. Do you understand that?

15 THE DEFENDANT: Yes, your Honor.

16 THE COURT: You have a constitutional right to the
17 processes of this court to compel the attendance of witnesses
18 in your own behalf. Do you understand that?

19 THE DEFENDANT: Yes, your Honor.

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THE COURT: You have a constitutional right to the assistance of counsel, which right you have exercised, and you have a constitutional right to remain silent and not be compelled to incriminate yourself or the corporation. Do you understand that?

25 THE DEFENDANT: Yes.

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4 THE DEFENDANT: Yes, your Honor.

5 THE COURT: I wish, also, to advise you that you
6 are not required to establish your innocence, the innocence of
7 the corporation, um, but it's the duty of the Government to
8 prove their case beyond a reasonable doubt. Do you understand
9 that?

10 THE DEFENDANT: Yes, your Honor.

THE COURT: When you're pleading guilty, you are giving up the so-called presumption of innocence. Do you understand that?

THE DEFENDANT: Yes, your Honor.

15 THE COURT: Have you advised your attorney of all
16 the circumstances surrounding the charge pending against you
17 and the corporation?

THE DEFENDANT: Yes, your Honor.

19 THE COURT: Has he advised you as to the nature of
20 those charges and any possible defense you or the corporation
21 might have?

THE DEFENDANT: Yes, your Honor.

THE COURT: what is the penalty provided by statute
for the offenses to which the individual defendant, the
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25 corporate defendant is pleading guilty to?

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1 MS. CARMODY: Your Honor, on the charge of
2 conspiracy, the defendant is subject to a term of imprisonment
3 for five years, a fine of \$250,000, a term of supervised
4 release of three years, and a mandatory special assessment of
5 100 dollars. With respect to the corporation, your Honor, the
6 corporation is subject to a fine of \$500,000, or twice the
7 gross gain or loss involved in the event, whichever is greater,
8 or both, and a special assessment of 400 dollars.

9 THE COURT: You understand that that's the
10 statutory penalty provided for the offenses for which you and
11 the corporation are pleading guilty?

12 THE DEFENDANT: Yes, your Honor.

13 THE COURT: Has anyone threatened you to change
14 your plea to guilty?

15 THE DEFENDANT: No, your Honor.

16 THE COURT: Was there any plea bargain involved in
17 this case?

18 MS. CARMODY: Yes, your Honor.

19 THE COURT: And would you advise the Court what
20 that plea bargain consists of?

21 MS. CARMODY: Yes, your Honor. We have filed
22 earlier today with the Court a plea agreement for both the
23 individual, Rudolph J. Liedtke, as well as the corporation.
24 With respect to Mr. Liedtke, your Honor, there is a sentencing
25 guidelines calculation that would indicate that his guideline

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1 range would be between 30 and 37 months. Um, that the
2 Government's plea agreement calls for a base offense level of

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6, an enhancement of 16, for the amount of the fraud involved
with respect to this case, your Honor. Um, we have valued the
loss at somewhere between, at least, approximately, I would
say, your Honor, 2 million dollars, 2.63 million dollars. With
respect to the Government's recommendation, your Honor, we
intend, based on the defendant's cooperation, to file a 5K-1
motion. Failing that, your Honor, the Government would
recommend a term of imprisonment at the low end of the
guidelines. But we fully expect -- the defendant has agreed to
cooperate and that we will be filing that motion at the
appropriate time with respect to the individual.

THE COURT: How about with respect to the
corporation, what is the recommendation, according to the plea
agreement, that you will make with respect to the corporate
entity?

MS. CARMODY: With respect to the corporate entity,
your Honor, we have made a determination preliminarily based on
the corporate defendant's asserted inability to pay any fine,
and that they have provided documents that support that
assertion, that the recommendation under the plea agreement
would be that the corporation pay a fine in the amount of
\$5,000. Um, should the corporation be found to have the
ability to pay -- we haven't even determined the guidelines

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1 based on the inability to pay. But should that not be found to
2 be the case down the end of the road, we will recommend a
3 sentence at the low end of the guideline range.

THE COURT: A fine at the low end?

MS. CARMODY: A fine, yes.

THE COURT: Has this plea agreement been reduced to
writing?

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8 MS. CARMODY: It has, your Honor. We have filed
9 both a copy of the individual and the corporate agreement with
10 the Court.

11 THE COURT: I see. And just so the record is
12 clear, did you sign that plea agreement with the full
13 understanding of its contents?

14 THE DEFENDANT: Yes.

15 THE COURT: And did you sign it after consulting
16 with your attorney?

17 THE DEFENDANT: Yes.

18 THE COURT: A reference has been made to a
19 sentencing commission guideline factor. Um, as we know, as a
20 result of the Booker case, the guidelines, at this time, are
21 advisory, but they are a factor which the sentencing court will
22 take into consideration. Do you understand that?

23 THE DEFENDANT: Yes, your Honor.

24 THE COURT: Have you had an opportunity to discuss
25 with your attorney how the advisory sentencing commission

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1 guidelines might apply to your case?

2 THE DEFENDANT: Yes, your Honor.

3 THE COURT: And has he advised you that the exact
4 guideline range applicable to your case cannot be specifically
5 decided until after a presentence report has been concluded?

6 THE DEFENDANT: Yes, your Honor.

7 THE COURT: And you understand that the Court, um,
8 even though the guidelines are advisory, um, will take them in
9 consideration and either enhance the guideline sentence or
10 depart downward from that guideline range?

11 THE DEFENDANT: I understand that.

12 THE COURT: All right. Is the plea that you're

13 offering here today, on behalf of yourself and on behalf of the
14 corporate entity, entirely free and voluntary?

15 THE DEFENDANT: Yes, your Honor.

16 THE COURT: Take the plea.

17 THE CLERK: Rudolph J. Liedtke and RJL Sciences,
18 Inc., doing business as RJL Systems, Inc., as to Count 1 of an
19 information charging you with conspiracy to commit an offense
20 against the United States in violation of Title 18 USC Code
21 Section 371, how do you plead, guilty or not guilty?

22 THE DEFENDANT: Guilty.

23 THE COURT: I think the record, even at this stage,
24 should show that you understand that you have the
25 constitutional right to be charged by way of indictment, but

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1 knowing that, you willingly waive to be prosecuted by way of
2 indictment. Is that correct?

3 MR. KALEC: By way of information.

4 THE COURT: By way of information. Are you willing
5 to be tried or to plea to an information, notwithstanding the
6 fact that you have a constitutional right to be prosecuted by
7 way of indictment, but you are pleading here to an
8 information. You do that knowingly and willingly, realizing
9 that you have such a constitutional right?

10 THE DEFENDANT: Yes, your Honor.

11 THE COURT: I would ask the Government to briefly
12 set forth the evidence which it would have introduced were the
13 case to have gone to trial. You may sit down.

14 MS. CARMODY: Your Honor, I would like to say that
15 this is a medical device case and it's quite a complex case.
16 The parties have filed an agreed statement of facts with the
17 Court which sets forth the facts in great detail. So without

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18 going into all of the details in the agreed statement of facts,
19 should the case have gone to trial, the Government would have
20 proved that the defendant, RJL Sciences, doing business as RJL
21 Systems -- and I'll refer to them as "RJL," is located in
22 Clinton Township, Michigan. That RJL manufactured and sold
23 medical devices, including a Bioelectrical Impedance Analysis
24 known as a BIA device, and computer software for use in
25 connection with a BIA device.

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1 Commencing in 1996, RJL manufactured and sold the BIA
2 device and computer software together with and pursuant to
3 others who are not specifically named in the information, but
4 for whom the Court -- we have filed with the Court an in-camera
5 submission that will identify, for the Court's purposes, who
6 those entities are. Mr. Liedtke was the President and
7 principal owner of RJL and Mr. Liedtke directed, participated
8 and controlled and manufactured the sale of the BIA devices as
9 well as the software devices.

10 The BIA device, manufactured by the defendant, is a
11 portable device. It has two protruding electrodes. And in
12 order to perform the BIA test, the electrodes are placed on the
13 hands and feet of a human test subject and there's a very low
14 level electrical current that's run through the body. This
15 measures -- it encounters impedance and it measures the
16 reactance and resistance of the current as it flows through the
17 body. These measurements, um, generated by the BIA device,
18 were used to estimate the body's composition of humans.
19 Estimates of body compositions were computed by applying these
20 measurements generated by the BIA device to predictive
21 equations.

22 In other words, your Honor, the test is performed on a

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23 human and the device itself gives two measurements, reactance
24 and resistance and the individual performing the test then
25 takes those two numbers and transforms them, takes them and

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1 inputs them into a computer with computer software.
2 Incorporated in the computer software is a predictive equation
3 that then gives different values as a result of that test
4 measurement. And those measurements are measures of human body
5 composition, lean body mass, fat free mass, and in some
6 instances with respect to this case body, cell mass and other
7 measurements.

8 These predictive equations, which actually give the
9 ultimate measurements, were developed mathematically,
10 calculating the statistical relationship between the resistance
11 and reactance measurement obtained by the BIA test on a sample
12 population of human subjects, actual measurements of body
13 composition for that population. Prediction equations are used
14 to estimate the body composition of humans and it varies
15 depending on the characteristics and size of the sample
16 population used to develop the equation as well as on the
17 methodology used to measure the body composition within that
18 population.

19 The defendant participated in the development and
20 distribution of various BIA software devices and computer
21 software. In other words, the device stayed essentially the
22 same, your Honor, but it's the computer software packages that
23 took the measurements and used them to -- with a predictive
24 equation to give other values. Um, those changed over time.
25 And those computer software were known as -- one is known as

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1 "Body Comp," one is known as "Weight Manager," another is known
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2 as "Fluid and Nutrition," another is known as "Cyprus," and
3 another computer software we'll refer to as the "Y Software,"
4 and they were all used to estimate body composition in humans.
5 The BIA, as well as the computer software devices, were each
6 medical devices within the meaning of the Federal Food, Drug
7 and Cosmetic Act, 21 USC Section 321(H).

8 In order to sell these devices, the defendants could not
9 sell them legally without first obtaining premarket clearance
10 and/or premarket approval from the U.S. Food & Drug
11 Administration. And it depended -- that approval, whether or
12 not it was a clearance or an approval, depended upon the
13 intended use for which the device was to be put. The FDA could
14 grant what was called a 510(K) premarket clearance if it
15 determined, following a review of the information submitted, it
16 supported the premarket notification that the device was
17 substantially equivalent to a device that was in existence and
18 marketed in interstate commerce prior to May 26th, 1976. That
19 device would be known as a "predicate device." In other words,
20 if the device preexisted the passage of this section of the
21 Food, Drug and Cosmetic Act, then the FDA could clear it. But
22 that only happened if, among other things, the intended use of
23 the current device was the same intended use as the predicate
24 device. So if the intended use of the device was different
25 from the predicate device, a substantial equivalent, which is

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1 what the FDA would have to find, it could not be cleared,
2 because it would be a different use.

3 Um, premarket approval and review by the FDA generally
4 entailed, among other things, a review of clinical trials and
5 scientific data offered to confirm the safety and the efficacy
6 of the device as well as a review of the device's labeling, and
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7 it also has to include adequate directions for use. In 1983,
8 the defendants, RJL and Liedtke, filed a 510(K) premarket
9 notification with the FDA's Center for Devices and Radiological
10 Health, seeking premarket clearance for a Body Composition
11 Analyzer, a type of BIA device that was manufactured and sold
12 by RJL. In that 510(K) submission, the defendant stated that
13 the intended use of the BIA device was to estimate total body
14 water, lean body mass, also known as fat free mass, and fat in
15 healthy humans. RJL's BIA device was accompanied by a hand-
16 held programmable calculator and computer to facilitate the
17 computation of the estimated total body water, lean body mass,
18 and fat. After a review of the data submitted in support of
19 that 510(K) submission, the FDA found that the Body Comp
20 Analyzer was substantially equivalent to a device that had been
21 marketed prior to the FDCA Medical Device Amendments of 1976,
22 and they granted premarket clearance to RJL to distribute the
23 device on August 11th, 1983 for the intended use of estimating
24 total body water, lean body mass, and fat in healthy humans,
25 and that was the limitation.

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1 During a subsequent inspection of RJL, by the FDA, in
2 1984, the FDA discovered that RJL had been marketing a modified
3 version of the BIA device as well as a computer software device
4 that had not been previously reviewed by the FDA as part of a
5 510(K) submission. The FDA issued a Notice of Adverse Findings
6 to the defendant, RJL and Liedtke, in January of 1986,
7 informing them that the 1984 inspection revealed that they had
8 been marketing misbranded devices, specifically the modified
9 BIA device and the accompanying computer software device in
10 violation of the FDCA. In response to the Notice of Adverse
11 Findings, the defendant submitted another 510(K) premarket

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12 notification for the modified BIA device as well as for the new
13 computer -- the computer software device, accompanying the BIA
14 device on June 24th, 1986.

15 RJL and Liedtke told the FDA that the computer software
16 only performed calculations that previously would have been
17 done by hand to estimate body composition and that the Body
18 Comp Analyzer and its accompanying computer software had the
19 same intended uses as that previously submitted BIA device for
20 estimating total body water, lean body mass, and fat. The
21 defendants told the CDRH that the intended uses of the BIA
22 device, accompanying this computer software, did not include
23 measuring body cell mass or diagnosing any disease state. The
24 defendants also described the methods used to develop the
25 prediction equations in the computer software and told CDRH

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1 that the equations were based on a population consisting of 278
2 healthy and obese college students whose body composition was
3 measured through hydrostatic weighing and that total body water
4 measurements of the college students were determined using
5 deuterium oxide dilution, in other words, underwater weighing,
6 your Honor.

7 Based on the representations made by the defendants, RJL
8 and Liedtke, in their 510(K) submission and related
9 communications, the CDRH concluded that the modified Body Comp
10 Analyzer and accompanying computer software were substantially
11 equivalent to a device marketed prior to the Medical Device
12 Amendments of 1976 and they granted premarked clearance to RJL
13 to distribute the Body Comp Analyzer and the accompanying
14 computer software devices on February 3rd, 1987 for the
15 intended uses of estimating total body water, lean body mass,
16 and fat in healthy humans. At that time, the computer software

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17 device was called "Body Comp." Later versions of the RJL
18 software, with similar intended uses, were called "Weight
19 Manager."

20 Beginning in, at least, 1994, the defendant, RJL and
21 Liedtke, assisted others in developing a prediction equation
22 that would calculate the BIA resistance and reactance
23 measurements into estimated body cell mass. This equation,
24 which we'll refer to as the Z equation, estimated body cell
25 mass based on measurements of total body potassium in a

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1 population that we're going to refer to as the ABC database.
2 That database consisted of approximately 332 humans, including
3 individuals who were healthy, and others who had tested HIV
4 positive. Beginning, again, in sometime during 1994, the
5 defendants, RJL and Liedtke, developed new computer software
6 for use in interpreting BIA test results that incorporated the
7 Z equation and marketed the software under the name "Fluid and
8 Nutrition Analysis" or FNA. The FNA software purported to
9 calculate the individual test subject's estimated body cell
10 mass, total body water, intracellular and extracellular water,
11 fat free mass, extracellular tissue and fat. The FNA software
12 also computed purported "normal ranges" for the individual test
13 subject's total body water and intracellular water and
14 extracellular water. These normal ranges were calculated by
15 the defendant, RJL and Liedtke, by comparing the individual BIA
16 test results to a select portion of the population included in
17 this ABC database.

18 This FNA software, pursuant to 21 USC Section
19 351(f)(1)(B)(I) required FDA approval before it could be
20 legally marketed. No application for premarket approval has
21 been submitted to the FDA with respect to the FNA software and

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22 the device has never been the subject of an approved
23 application for premarket approval under 21 USC Section
24 350(E). Others marketed and sold the drug known to the United
25 States Attorney and referred to herein as "the drug," which was

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1 approved by the FDA to treat AIDS wasting, a condition
2 involving profound involuntary weight loss in AIDS patients.
3 At the time the FDA approved the drug, AIDS wasting was an
4 AIDS-defining condition.

5 On or about January of 1995, the defendants met with
6 others regarding the possible use of BIA technology by, um,
7 others known and unknown to the U.S. Attorneys. Thereafter,
8 between September 1995 and June 1996, the defendant, RJL,
9 shipped approximately 25 BIA devices together with the FNA
10 Version 3.1 software packages to others known and unknown for
11 use in evaluating the body composition in AIDS patients.
12 Commencing as early as September 1996 and continuing thereafter
13 until about January 2002, the defendants, and others knowingly
14 -- and others, knowingly and willfully, combined and conspired
15 and agreed to commit an offense against the United States, that
16 is, the parties to this conspiracy agreed to introduce or
17 deliver for introduction or cause to be introduced or delivered
18 for introduction into interstate commerce and did, in fact,
19 introduce and cause to be introduced and delivered for
20 introduction into interstate commerce with the intent to
21 defraud and to mislead, adulterated medical devices, those
22 devices being the computer software packages that accompanied
23 the BIA device.

24 Specifically, these adulterated devices were BIA
25 computer software packages known as "FNA," known as "Y

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1 Software" and "Cyprus." They were for use in calculating body
2 cell mass and/or diagnosing AIDS wasting based upon BIA
3 resistance and reactance measurements. So that was a new
4 intended use, your Honor. These devices were adulterated
5 within the meaning of Title 21, USC, Section 351(F)(1)(B)(I),
6 and that neither RJL nor Liedtke nor others obtained premarket
7 approval from the FDA to introduce such medical devices into
8 interstate commerce. And this was all in violation of 18 USC
9 Section 371, Title 21, USC, Section 331(A) and 333(A)(2).

10 It was the purpose of this conspiracy that RJL and
11 Liedtke, with others, introduced or delivered for introduction
12 or caused to be introduced or to be delivered for introduction
13 into interstate commerce adulterated devices in order to
14 increase the market for BIA devices and computer software and
15 to increase the market for the drug. To that end, RJL and
16 Liedtke and others participated in the development and
17 dissemination of BIA computer software that purported to
18 measure body cell mass for use in diagnosing AIDS wasting based
19 upon a test subject's purported loss of body cell mass. The
20 disease state of AIDS wasting, which the drug was tested and
21 approved by the FDA, consisted of profound involuntary weight
22 loss and loss of lean body mass in AIDS patients and did not
23 include the loss of body cell mass. The use of BIA computer
24 software that purported to measure the loss of body cell mass
25 enabled RJL and Liedtke and others to expand the market for BIA

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1 devices and computer software devices and for others to expand
2 the market for the drug beyond this disease state for which the
3 drug was tested and approved.

4 This conspiracy operated through various manner and

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means. It was part of the conspiracy to disseminate BIA devices and FNA software to others in order to promote the diagnosis of AIDS wasting as a disease state involving the loss of lean body mass and to thereby promote the prescribing and sale of the drug. The FNA software was not submitted to the FDA for premarket approval. It was not approved by the FDA for shipment in interstate commerce for the intended use of measuring body cell mass or diagnosing in AIDS wasting. The inclusion of the Z equation and the ABC database in the FNA software and the use of the computer software to measure body cell mass as a tool for diagnosing AIDS wasting were new intended uses that required premarket approval from the FDA before their introduction or delivery for introduction into interstate commerce. It was also part of the conspiracy to develop and disseminate the Y software to others in order to promote the diagnosis of --

THE COURT: So, in essence, what you're saying is that there has been a new intended use and that was not approved?

MS. CARMODY: Exactly, your Honor. And there were several versions of the software with respect to the BIA. So

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it continued through the FNA software, to the Y software, which had a different population base, that employing the NHANES database rather than the population base of the ABC database, and it used "ideal" measurements and not "normal" measurements in that software. And that was a --

THE COURT: Let me ask you this question. Is an application for this -- for these new intended uses that have not been approved been sought?

MR. CARMODY: No, your Honor.

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10 THE COURT: No new application whatsoever?

11 MR. CARMODY: None, your Honor.

12 So it went through the Y software and then it continued
13 through the Cyprus software, which is the last version of the
14 software, again, using the equation and the NHANES database,
15 which was a new database.

16 Um, in addition, your Honor, the parties to the
17 conspiracy engaged in certain overt acts in furtherance of --

18 THE COURT: You don't have to give me all the overt
19 acts.

20 MS. CARMODY: Okay. Generally, your Honor, there
21 were meetings here in Massachusetts, looking for the
22 Massachusetts connection, in which the company that sold the
23 drug is located here in Massachusetts and the defendants came
24 and met with employees of the company, here in Massachusetts,
25 to discuss and to take action with regard to the dissemination

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1 of the adulterated devices. And that continued through March
2 1997 and up through and including 2002.

3 THE COURT: All right. Let me ask counsel for the
4 defendant, you've heard the representations made by the United
5 States as to the acts which constitute the violation of law.
6 Is there anything that you wish to contest or to add?

7 MR. KALEC: No, your Honor, outside of what was
8 submitted in the stipulated statement attached, which was not
9 read into the record by the Assistant United States Attorney.

10 THE COURT: The entire statement of facts is part
11 of the record in the case, though, that's been submitted?

12 MS. CARMODY: Yes, your Honor. We have an agreed
13 statement of facts. I have not read the entire statement of
14 facts, but I've read three quarters of it. And it is filed in

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the record, your Honor.

THE COURT: I understand that you can't promote or sell medical devices that have not been approved. That's the core of the violation. My additional question is, has this device caused any harm, is it harmful, in addition to being not approved? Do you understand? I understand that medical devices have to be approved and the failure to have them approved is itself a violation of law. But sometimes, in addition thereto, the device causes harm. Is there any -- is that factor here in this case or not?

MS. CARMODY: The way it factors in, your Honor --

the test itself is harmless. The test itself did not, in any way, cause the patient pain or harm. The harm is the fraud on -- in particular, the Medicaid system. This particular drug was paid for, 75 to 80 percent, by the state Medicaid program throughout the United States. It was a very expensive drug. And so patients, by virtue of this test, who got the drug when they otherwise should either not have gotten the drug or would not have qualified to get the drug, that, therein, lies the harm, your Honor.

10 THE COURT: Do you wish to add anything?

11 MR. KALEC: No, your Honor. There was no physical
12 harm to any patient.

17 MR. KALEC: That is correct, your Honor.

18 THE COURT: And that's when you say that the loss
19 or the financial harm is in the area of -- I think you

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indicated 2 million dollars?

21 MS. CARMODY: Well, that's an important point, your
22 Honor. I want to make an important distinction here. And you
23 can see, in the plea agreement, because we go into considerable
24 detail with respect to what was going on here, um, that the
25 defendant conspired with the company to disseminate the

□ 25

1 adulterated devices and that increased the sales of the drug.
2 And in the plea agreement, at Page 3, we talk about the fact
3 that -- and I think it's an important distinction here, that
4 the defendant committed some act with respect to the company,
5 but the company also committed independent acts of fraud that
6 were not reasonably foreseeable to this defendant. So that in
7 terms of the sale of the devices from August 14th, 1995 through
8 January 15th, 2002, the total price paid by the company for the
9 sale of these devices was a little over a million dollars,
10 \$1,031,583.25. In Paragraph 4 on Page 3, it says, in
11 determining the guideline calculation: "The Government
12 contends that from 1997 to 2002, the company received more than
13 100 million dollars in sales for this drug." However, at the
14 end of that paragraph, the Government takes the position that
15 -- and the parties agree that it was reasonably foreseeable
16 that many of the acts of fraud committed by the company and its
17 employees were not known or reasonably foreseeable to this
18 defendant. So that it was reasonably foreseeable, however,
19 that the sales of the drug would increase as a result of the
20 use of the devices. It is impossible to calculate, your Honor,
21 exactly where you factor that in. So that the parties have
22 agreed that the total fraud loss that was reasonably
23 foreseeable would have been at least equal to the amount of the
24 sale of the devices, otherwise the company wouldn't have

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invested in a device where it was going to lose money,

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1 basically. So that's where we come to a figure of
2 approximately 2 million dollars in fraud loss with respect to
3 the adulterated devices.

4 THE COURT: Anything further?

5 MR. KALEC: No, your Honor.

6 THE COURT: All right. I'd ask the defendant, are
7 you presently under a doctor's care?

8 THE DEFENDANT: No, your Honor.

9 THE COURT: Have you taken any medicine, pills or
10 drugs today?

11 THE DEFENDANT: No, your Honor.

12 THE COURT: Have you ever been under psychiatric
13 care?

14 THE DEFENDANT: No, your Honor.

15 THE COURT: So you understand the nature of these
16 proceedings and that you've pled guilty to the one count
17 information, both on your own behalf and on behalf of the
18 corporation?

19 THE DEFENDANT: Yes, your Honor.

THE COURT: Counsel, do you know any reason why the Court should not accept the pleas of guilty?

22 MR. KALEC: None, your Honor.

23 THE COURT: I'm going to ask the defendant. Have
24 you had sufficient time to discuss this matter with your
25 attorney?

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1 THE DEFENDANT: Yes, your Honor.

THE COURT: And are you satisfied with his representation of you?

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4 THE DEFENDANT: Yes, your Honor.

5 THE COURT: I find that the pleas have been
6 voluntarily and knowledgeably offered with an understanding of
7 their possible consequences. I further find that there is an
8 independent basis for accepting the pleas and therefore
9 I accept the pleas of guilty and order that they be entered in
10 this case.

11 Disposition in this case is set for -- what is the
12 date? September 13th 2005 at 2:00. Any need for bail?

13 MR. KALEC: Your Honor, we met with Pretrial
14 Services this morning. I have reviewed his report. The
15 recommendation is personal recognizance with a condition that
16 Mr. Liedtke not apply for a passport and travel be limited to
17 the United States. We'd ask the Court to accept the
18 recommendation from Pretrial.

19 MS. CARMODY: No objection, your Honor.

20 THE COURT: All right. So ordered. All right.
21 I'll see you on the 13th of September.

22 (Adjourned, 2:45 p.m.)

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1 C E R T I F I C A T E

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7 I, RICHARD H. ROMANOW, OFFICIAL COURT REPORTER, do
8 hereby certify that the foregoing record is a true and
accurate transcription of my stenographic notes on
Page 23

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9 Tuesday, April 19, 2005 before Honorable Edward F.
Harrington, to the best of my skill and ability.

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16 RICHARD H. ROMANOW

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